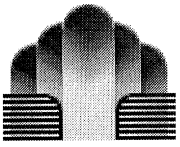
201-14423



Peter Wendolkowski
04/30/2003 10:47 AM

To: Peter Wendolkowski/DC/USEPA/US@EPA
cc:
cc:
Subject: Environmental Defense comments on 2-Propenamide, N-(1,1,3,3-tetramethylbutyl) (CAS# 4223-03-4)

Richard_Denison@environmentaldefense.org on 04/25/2003 09:50:55 AM

To: oppt.ncic@epamail.epa.gov, hpv.chemrtk@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA, Karen Boswell/DC/USEPA/US@EPA, hpvchallenge@covance.com
cc: lucierg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on 2-Propenamide, N-(1,1,3,3-tetramethylbutyl) (CAS# 4223-03-4)

(Submitted via Internet 4/25/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and hpvchallenge@covance.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 2-Propenamide, N-(1,1,3,3-tetramethylbutyl) (CAS# 4223-03-4).

The test plan and robust summaries were prepared by the National Starch and Chemical Company of ICI Americas. It is a somewhat unusual test plan inasmuch as there are few available data for the requested SIDS endpoints. 2-Propenamide, N-(1,1,3,3-tetramethylbutyl) (PBNTB) is used in a variety of polymers that are incorporated into hairspray, various skin care products and other products. The sponsor states that PBNTB itself has no consumer uses, and that therefore, there is little opportunity for consumer exposure, although occupational exposure potential does exist. The sponsor proposes to conduct studies on most HPV endpoints; in general, we agree with the test plan, although we do propose some modifications to it. Specific comments are as follows:

1. The sponsor and the NMA/NBMA Association have previously submitted a test plan on acrylamide derivatives. The sponsor has wisely made the decision not to include PBNTB as part of the acrylamide category, as it possesses physicochemical and genetic toxicity properties distinct from those of members of the acrylamide derivatives category.

2. The sponsor proposes to conduct studies on all physicochemical endpoints. We agree with this proposal.

3. Environmental fate and behavior studies are proposed for all HPV endpoints except photodegradation, where data already exist. We agree with this proposal.

4. The full spectrum of ecotoxicity studies are proposed. Because there are no existing studies on these endpoints, we agree with the proposal.

5. The only mammalian toxicity endpoints that have adequate data are the genetic toxicity endpoints. The sponsor proposes to conduct acute toxicity, repeat dose and reproductive studies, potentially to be followed by a fertility study depending on the outcome of the repeat dose and

reproductive studies. We recommend a modified plan whereby the sponsor would conduct a combined repeat dose/reproduction/development study for PBNTB. In addition, we do not think that an acute toxicity study is needed, since high-dose toxicity will be detected by the preliminary range-finding study conducted prior to the combined repeat dose/reproductive/developmental study. This modified approach will provide more data more quickly and will require the sacrifice of fewer laboratory animals.

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense